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wherein X, Y and Z are selected from the group consisting of hydrogen, C₁-C₃ alkyl group, C₂-C₄ alkanol group;

wherein at least one of X, Y or Z is a C₂-C₄ alkanol group bearing at least one hydroxyl group and optionally at least one carboxyl group; and

wherein said skin irritating composition comprises at least one compound selected from the group consisting of retinoid, benzoyl peroxide, salicylic acid, surfactants, soaps, natural plant extracts, sunscreen actives and preservatives.

REMARKS

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Claims 1-16 are pending in this application. The Examiner has rejected:

- (1) claims 7 and 16 under 35 U.S.C. § 112 (second paragraph);
- (2) claims 1-16 over US-A-6,162,419 ("Perricone I" reference") under 35 U.S.C. §§ 102(a) and 102(e); and
- 15 (3) claims 1-16 over US-A-5,643,586 ("Perricone II" reference") under 35 U.S.C. §§ 102(b) and 103(a).

Applicants are herein amending claims 1, 6, 9, 10 and 11 and cancelling claims 7, 8 and 16, without prejudice, leaving claims 1-6 and 9-15 pending after entrance of this amendment.

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Applicants are herein amending claim 1 to more specifically point out and distinctly claim that a select composition is applied to red or inflamed skin. Support for the amendment may be found on page 7, lines 18-28 and cancelled claim 8.

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Applicants are herein amending claims 6 and 11 to require that the skin irritating ingredient is selected from the group consisting of retinoid, benzoyl peroxide, salicylic acid, surfactants, soaps, natural plant extracts, sunscreen actives and preservatives. Support for the amendment may be found in cancelled claims 7 and 16.

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Applicants are herein amending dependent claims 9 and 10 to insert that they depend from claim 1, rather than cancelled claim 8.

Applicants are herein amending claim 11 to more specifically point out and distinctly claim the subject matter of their invention. Support for the second clarification is found in the specification at page 13, lines 12-15.

5 Applicants submit that the amendment to the claims does not introduce new matter and is fully supported by the specification and claims, as originally filed. Applicants request the Examiner to enter the amendment under 37 C.F.R. § 1.116(b) because the amendments to the claims either cancel claims, comply with requirements of form expressly set forth in a previous Office Action, or present the rejected claims in better form for consideration on
10 appeal.

Rejection under 35 U.S.C. § 112 (second paragraph)

15 The Examiner has maintained the rejection of claims 7 and 16 under 35 U.S.C. § 112 (second paragraph) that the use of the phrase "natural plant extracts" renders the claims vague and indefinite. Even though applicants have cancelled claims 7 and 16, the limitations of both claims, including "natural plant extracts" have been incorporated into pending claims 6 and 11. Applicants respectfully traverse that the phrase is vague and indefinite. Applicants
20 submit that one skilled in the art of skin care compositions would fully appreciate and know which natural plant extracts cause skin irritation and thus would be able to add the select compositions when such natural plant extracts were present in the composition to alleviate skin irritation that would result from application of the composition to the skin.

25 Applicants submit that claims 6 and 11 are not vague and indefinite for use of the phrase "natural plant extract" and request the Examiner to withdraw the rejection of the claims under 35 U.S.C. § 112 (second paragraph).

Rejection under 35 U.S.C. §§ 102(a) and 102(e) over US-A-6,162,419 ("Perricone I" reference)

30 The Examiner has maintained the rejection of claims 1-16 under 35 U.S.C. §§ 102(a) and 102(e). Applicants respectfully traverse because *Perricone I* does not disclose each and

every element of applicants' claimed invention, as amended, and thus does not anticipate claims 1-6 and 9-15, as amended, under 35 U.S.C. §§ 102(a) or 102(e).

Independent claim 1, as amended, is directed to a method that requires the step of 5 topically applying a composition of alkanolamine, tyrosine or mixtures thereof to red or inflamed mammalian skin. Applicants submit that *Perricone I* does not disclose any step of applying any composition to red or inflamed skin. Rather, *Perricone I* discloses compositions containing vitamin C-based compounds and the application thereof to the skin. *Perricone I*'s compositions may also contain dimethylaminoethanol (DMAE) and tyrosine. 10 *Perricone I* discloses that DMAE is added for its skin tightening and smoothing effects on the skin and that tyrosine is added to provide a silk feeling to the composition. However, *Perricone I* never discloses the application of the composition containing both DMAE and tyrosine to skin that is red or inflamed. Accordingly, *Perricone I* cannot anticipate claim 1 and its dependent claims because it fails to disclose each and every element of the claims.

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Independent claim 11, as amended, is directed to a method that requires the step of adding alkanolamine, tyrosine or mixtures thereof to compositions that contain ingredients that cause skin irritation, wherein such ingredients are limited to retinoid, benzoyl peroxide, salicylic acid, surfactants, soaps, natural plant extracts, sunscreen actives and preservatives. 20 Applicants submit that *Perricone I* does not disclose any step of adding DMAE, tyrosine or mixtures thereof to compositions containing specific skin irritants. Accordingly, *Perricone I* cannot anticipate claim 11 and its dependent claims because it fails to disclose each and every element of the claims.

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Applicants submit that *Perricone I* does not anticipate claims 1-6 and 9-15, as amended, and request the Examiner to withdraw the rejection under 35 U.S.C. § 102(b) over *Perricone I*.

Rejection under 35 U.S.C. § 102(b)//35 U.S.C. § 10(a) over US-A-5,643,586 (“*Perricone II* reference”)

The Examiner has maintained the rejection of claims 1-16 as anticipated by US-A-5,643,586 (“*Perricone II* reference”) under 35 U.S.C. § 102(b) or, alternatively, as obvious over *Perricone II* under 35 U.S.C. § 103(a). Applicants respectfully traverse because:

- (a) *Perricone II* does not disclose each and every element of applicants’ claimed invention, as amended; and
- (b) *Perricone II* does not teach or suggest applicants’ claimed invention, as amended, and thus does not render obvious claims 1-6 and 9-15, as amended.

To establish a proper *prima facie* rejection, the Examiner must show:

- (1) the references which are available as prior art against the claimed invention;
- (2) the motivation (explicit or implicit) provided by the references that would have rendered the claimed invention obvious to one of ordinary skill in the art at the time of the invention;
- (3) a reasonable expectation of success;
- (4) the basis for concluding that the claimed invention would have been obvious to do, not merely obvious to try; and
- (5) the references teach the claimed invention as a whole.

Applicants submit that the Examiner has not established elements 2, 3, 4 and 5. If the Examiner fails to establish any one of these elements, he has not made a proper *prima facie* obviousness rejection and the applicants are entitled to a patent. *In re Grabiak*, 769 F.2d 729, 733, 226 U.S.P.Q. 870, 873 (Fed. Cir. 1983).

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With respect to independent claim 1, applicants submit that one skilled in the art would not be motivated explicitly or implicitly, upon reading *Perricone II*, to use the composition disclosed therein in a method to treat red or inflamed skin.

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Perricone II discloses a method for treating aging skin and subcutaneous muscles including the step of topically applying to aged and sagging skin and muscles a composition containing catecholamine and related compounds in a dermatologically-acceptable to produce increased muscle tone. The *Perricone II* reference, while describing the application of the

composition to the skin of the face, does not disclose; teach or suggest any individual having, or any condition exhibiting, red or inflamed skin, as required by claim 1, as amended). Rather, *Perricone II* only discusses the muscle tone of subcutaneous muscle on the face and chest and the resultant shortening of muscles on the face and chest by applying the select composition. The shortening of the muscles results in a lifting of overlying skin, with the cosmetic appearance of diminished sagging. The crux of *Perricone II*'s invention lies in applying a select composition to enhance production of catecholamine and catecholamine-related compounds (including tyrosine) and help boost levels of acetylcholine in the neuromuscular junction, resulting in the increased muscle tone (column 8, line 59-column 9, line 8).

The redness and inflammation that the methods of applicants' invention are designed to treat, result from external causes (such as sun or wind burn or irritating soaps or cleansers) or inherent conditions (such as rosacea, atopic dermatitis or allergic skin reactions) (page 7, lines 23-26), not from a lack of muscle tone. Nothing that *Perricone II* discloses or suggests that it is even possible that its compositions or methods are useful to treat red or inflamed skin – pre-existing or caused by the ingredients in the composition itself. While both problems (*Perricone II*'s problem – sagging of skin and underlying muscle and applicants' problem – redness and inflammation on the skin pre-existing or after application of a skin irritant) involve the skin, the methods of applicants' invention require a step of applying a select composition to the red or inflamed skin (pre-existing or caused by specific ingredients in the composition itself) – not just to the skin of the face – a step that is non-existent in the *Perricone II* reference.

Furthermore, the missing elements in claim 1 (step of applying composition to red or inflamed skin) and claim 11 (step of applying composition contain select skin irritants – namely, retinoid, benzoyl peroxide, salicylic acid, surfactants, soaps, natural plant extracts, sunscreen actives and preservatives) are not inherent in the disclosure of *Perricone II* because it clearly treats a problem relating to muscle sag not redness or inflammation and never gives any indication that any of those treated had red or inflamed skin at the onset or by use of the compositions.

Applicants respectfully submit that:

- (a) *Perricone II* does not disclose each and every element of applicants' claimed invention, as amended, and thus does not anticipate claims 1-6 and 9-15, as amended, under 35 U.S.C. § 102(b); and
- 5 (b) *Perricone II* does not teach or suggest applicants' claimed invention, as amended, and thus does not render obvious claims 1-6 and 9-15, as amended, under 35 U.S.C. § 103(a).

Accordingly, applicants request the Examiner to withdraw the rejection of claim 1-6 and 9-15, as amended, as anticipated under 35 U.S.C. § 102(b), or in the alternative, as obvious
10 under 35 U.S.C. § 103(a).

Conclusions

Applicants request the Examiner to:

- 15 (1) enter the amendment; and
(2) reconsider and withdraw the rejection of claims 1-16; and
(3) pass claims 1-6 and 9-15, as amended, to allowance.

If the Examiner is of a contrary view, the Examiner is requested to contact the undersigned attorney at (215) 557-3861.
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Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE."

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the claims:

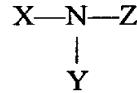
5 Please cancel claims 7, 8 and 16, without prejudice.

Please amend claims 1, 6, 9, 10 and 11, as follows:

1. (twice amended) A method for ameliorating redness or inflammation of mammalian
10 skin, comprising the step of [by] topically applying a composition to red or inflamed
mammalian skin, said composition comprising:

- (a) an effective amount of a redness or inflammation reducing agent selected from
the group consisting of an alkanolamine; tyrosine; or a mixture thereof; and
(b) a cosmetically acceptable carrier;

15 wherein said alkanolamine has the following general formula:



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wherein X, Y and Z are selected from the group consisting of hydrogen, C₁-C₃
alkyl group, C₂-C₄ alkanol group[,];

wherein at least one of X, Y or Z is a C₂-C₄ alkanol group bearing at least one
hydroxyl group and optionally at least one carboxyl group.

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6. (amended) A method according to claim 1, wherein said composition further comprises a
skin irritating ingredient selected from the group consisting of retinoid, benzoyl
peroxide, salicylic acid, surfactants, soaps, natural plant extracts, sunscreen actives
and preservatives.]]

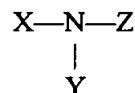
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9. (amended) A method according to claim [8] 1, wherein said composition is applied to sun
burned skin, wind burned skin, or skin that is red or inflamed due to contact with
irritating soaps or cleansers.

10. (amended) A method according to claim [8] 1, wherein said composition is applied to skin that is red or inflamed due to rosacea, atopic dermatitis, or allergic skin reactions.

11. (amended) A method for ameliorating the irritating effects of a skin irritating composition comprising adding to said composition an effective amount of a compound selected from the group consisting of an alkanolamine; tyrosine; or a mixture thereof; wherein said alkanolamine has the following general formula:

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wherein X, Y and Z are selected from the group consisting of hydrogen, C₁-C₃ alkyl group, C₂-C₄ alkanol group[.];

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wherein at least one of X, Y or Z is a C₂-C₄ alkanol group bearing at least one hydroxyl group and optionally at least one carboxyl group; and

wherein/said skin irritating composition comprises at least one compound selected from the group consisting of retinoid, benzoyl peroxide, salicylic acid, surfactants, soaps, natural plant extracts, sunscreen actives and preservatives.